

Notice of Allowability	Application No.	Applicant(s)	
	10/748,962	KOPF ET AL.	
	Examiner	Art Unit	
	Ana M. Fortuna	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/24/08.
2. ☒ The allowed claim(s) is/are 13-16, 19, 21-28 and 39.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>1/15/09</u> . 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input checked="" type="checkbox"/> Other <u>Figure drawings filed on</u> . |
|---|--|

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Marianne Fuierer 1/14/09.

The application has been amended as follows:

Cancel claims 1, 3-7, 9-12, and 29-38.

Amend the claims.

13. (Currently amended) An apparatus system for separating milk components and capturing a lactose rich fraction , comprising:

a milk source ;

one or more cross-flow filtration modules communicatively connected to said milk source, for generating one or more filtration fractions wherein the cross-flow filtration modules comprise a feed inlet, a retentate outlet, a permeate outlet, a multiplicity of filter sheets in an operative stacked arrangement, wherein the filter sheets alternate with permeate and retentate sheets, wherein the retentate sheet comprises multiple fluid-flow channels each extending between the feed inlet and retentate outlet, wherein the fluid flow channels are of equal length to one another as measured between the inlet and the outlet, and wherein as a liquid to be filtered flows across the filter sheets, solids or high-molecular-weight species of diameter larger than the filter sheet's pore size, are retained

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in the retentate flow, and the liquid along with any permeate species diffuse through the filter sheets and enter the permeate sheet to the permeate outlet;

wherein the system for capturing a lactose rich fraction comprises the following cross-flow filtration modules and fluid collection conduits:

an optional first cross-flow filtration module downstream of the milk source and communicatively connected thereto for filtering out all or at least a portion of bacteria contained in the milk;

a second cross-flow filtration module, downstream of the first cross-flow filtration module if the first cross flow filtration module is provided and communicatively connected thereto, or if the first cross flow filtration module is not the provided, then the second cross-flow filtration module is communicatively connected directly to the milk source, which separates the milk into a casein-rich fraction and a casein-depleted fraction;

a first fluid collection conduit connected to said second cross-flow filtration module for capturing the casein-rich fraction;

a third cross-flow filtration module downstream of the second cross-flow filtration module and communicatively connected thereto, which receives the casein-depleted fraction and further separates it into a fraction that is enriched with albumin and immunoglobulins and a fraction that is depleted of albumin and immunoglobulins;

a second fluid collection conduit connected to said third cross-flow filtration module for capturing the fraction that is enriched with albumin and immunoglobulins;

a fourth cross-flow filtration module downstream of the third cross-flow filtration module and communicatively connected thereto, which receives the fraction that is depleted of albumin and immunoglobulins and further separates it into a β -lactoglobulin-rich fraction and a β -lactoglobulin-depleted fraction;

a third fluid collection conduit connected to said fourth cross-flow filtration module for capturing the β -lactoglobulin-rich fraction;

a fifth cross-flow filtration module downstream of the fourth cross-flow filtration module and communicatively connected thereto, which receives the β -lactoglobulin-depleted fraction and further separates it into a α -lactalbumin-rich fraction and a α -lactalbumin-depleted fraction;

a fourth fluid collection conduit connected to said fifth cross-flow filtration module for capturing the α -lactalbumin-rich fraction;

a sixth cross-flow filtration module downstream of the fifth cross-flow filtration module and communicatively connected thereto, which receives the α -lactalbumin-depleted fraction and further separates it into a complex carbohydrates rich fraction and a complex carbohydrates depleted fraction;

a fifth fluid collection conduit connected to said sixth cross-flow filtration module for capturing the complex carbohydrates rich fraction;

a seventh cross-flow filtration module downstream of the sixth cross-flow filtration module and communicatively connected thereto, which receives the complex carbohydrates depleted fraction and further separates it into a lactose-rich fraction and a lactose-depleted fraction; and

a sixth fluid collection conduit connected to said seventh cross-flow filtration module for capturing the lactose-rich fraction;

a discharge conduit for discharging and/or recycling the lactose-depleted fraction.

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14. (Currently amended) An apparatus system for separating milk components and capturing an α -lactalbumin-depleted fraction comprising:

a milk source;

one or more cross-flow filtration modules communicatively connected to said milk source for generating one or more filtration fractions wherein the cross-flow filtration modules comprise a feed inlet connected to a fluid delivery conduit, a retentate outlet, a permeate outlet, a multiplicity of filter sheets in an operative stacked arrangement, wherein the filter sheets alternate with permeate and retentate sheets, wherein the retentate sheet comprises multiple fluid-flow channels each extending between the feed inlet and retentate outlet, wherein the fluid flow channels are of equal length to one another as measured between the inlet and the outlet, and wherein as a liquid to be filtered flows across the filter sheets, solids or high-molecular-weight species of diameter larger than the filter sheet's pore size, are retained in the retentate flow, and the liquid along with any permeate species diffuse through the filter sheets and enter the permeate sheet to the permeate outlet;

wherein the system for capturing an α -lactalbumin-depleted fraction comprises the following cross-flow filtration modules and fluid collection conduits:

~~an optional~~ a first cross-flow filtration module downstream of the milk source and communicatively connected thereto for filtering out all or at least a portion of bacteria contained in the milk;

a second cross-flow filtration module downstream of said first cross-flow filtration module or the milk source and communicatively connected to said first cross-flow filtration or the milk source, which separates the milk into a casein-rich fraction and a casein-depleted fraction;

a first fluid collection conduit connected to said second cross-flow filtration module for capturing the casein-rich fraction;

a third cross-flow filtration module downstream of the second cross-flow filtration module and communicatively connected thereto, which receives the casein-depleted fraction and further separates it into a β -lactoglobulin-rich fraction and a β -lactoglobulin-depleted fraction;

a second fluid collection conduit connected to said third cross-flow filtration module for capturing the β -lactoglobulin-rich fraction;

a fourth cross-flow filtration module downstream of the third cross-flow filtration module and communicatively connected thereto, which receives the β -lactoglobulin-depleted fraction and further separates it into a α -lactalbumin-rich fraction and a α -lactalbumin-depleted fraction;

a third fluid collection conduit connected to said fourth cross-flow filtration module for capturing the α -lactalbumin-rich fraction; and

a fourth fluid collection conduit connected to said fourth cross-flow filtration module for capturing the α -lactalbumin-depleted fraction for subsequent processing selected from the group consisting of cross-flow filtration, lactose recovery, discharging, recycling, capturing, further processing and recycling.

15. (Original) An apparatus according to claim 13, further comprising a pasteurizer upstream and/or downstream of any of the cross-flow filtration modules for pasteurizing the milk source or any one or more filtration fractions generated by the cross-flow filtration modules.
16. (Original) An apparatus according to claim 14, further comprising a pasteurizer upstream and/or downstream of any of the cross-flow filtration modules for pasteurizing the milk source or any one or more filtration fractions generated by the cross-flow filtration modules.

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17. -18. (Cancelled)

19. (Previously presented) An apparatus according to claim 16, further comprising temperature controller or monitor for controlling and monitoring temperature of said milk and/or filtration fractions generated by the cross-flow filtration modules.

20. (Cancelled)

21. (Original) An apparatus according to claim 16, further comprising a cream separator upstream of said cross-flow filtration modules for removing all or at least a portion of fatty component from the milk.

22. (Original) An apparatus according to claim [17] 15, further comprising a cream separator upstream of said cross-flow filtration modules for removing all or at least a portion of fatty component from the milk.

23. (Currently amended) An apparatus system for separating milk components and capturing an α -lactalbumin-rich fraction, comprising:

a milk source;

one or more cross-flow filtration modules communicatively connected to said milk source for generating one or more filtration fractions wherein the cross-flow filtration modules comprise a feed inlet connected to a fluid delivery conduit, a retentate outlet, a permeate outlet, a multiplicity of filter sheets in an operative stacked arrangement, wherein the filter sheets alternate with permeate and retentate sheets, wherein the retentate sheet comprises multiple fluid-flow channels each extending between the feed inlet and retentate outlet, wherein the fluid flow channels are of equal length to one another as measured between the inlet and the outlet, and wherein as a liquid to be filtered flows across the filter sheets, solids or high-molecular-weight species of diameter larger than the filter sheet's pore size, are retained in the retentate flow, and the liquid along with

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any permeate species diffuse through the filter sheets and enter the permeate sheet to the permeate outlet;

wherein the system for capturing an α -lactalbumin-depleted fraction comprises the following cross-flow filtration modules and fluid collection conduits:

an optional first cross-flow filtration module downstream of the milk source and communicatively connected thereto by a fluid delivery conduit wherein the first cross-flow filtration module is used for filtering out all or at least a portion of bacteria contained in the milk;

a second cross-flow filtration module, downstream of the first cross-flow filtration module if the first cross flow filtration module is in the system ~~provided~~ and communicatively connected thereto, or in the alternative if the first cross flow filtration module is not the provided, then the second cross-flow filtration module is communicatively connected directly to the milk source, which separates the milk into a casein-rich fraction and a casein-depleted fraction;

a first fluid collection conduit connected to said second cross-flow filtration module for capturing the casein-rich fraction;

a third cross-flow filtration module downstream of the second cross-flow filtration module and communicatively connected thereto, which receives the casein-depleted fraction and further separates it into a fraction that is enriched with albumin and immunoglobulins and a fraction that is depleted of albumin and immunoglobulins;

a second fluid collection conduit connected to said third cross-flow filtration module for capturing the fraction that is enriched with albumin and immunoglobulins;

a fourth cross-flow filtration module downstream of the third cross-flow filtration module and communicatively connected thereto, which receives the fraction that is depleted of

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albumin and immunoglobulins and further separates it into a β -lactoglobulin-rich fraction and a β -lactoglobulin-depleted fraction;

a third fluid collection conduit connected to said fourth cross-flow filtration module for capturing the β -lactoglobulin-rich fraction;

a fifth cross-flow filtration module downstream of the fourth cross-flow filtration module and communicatively connected thereto, which receives the β -lactoglobulin-depleted fraction and further separates it into a α -lactalbumin-rich fraction and a α -lactalbumin-depleted fraction;

a fourth fluid collection conduit connected to said fifth cross-flow filtration module for capturing the α -lactalbumin-rich fraction;

a fifth fluid collection conduit connected to said fifth cross-flow filtration module for capturing the α -lactalbumin-depleted fraction for subsequent processing selected from the group consisting of cross-flow filtration, lactose recovery, discharging, recycling, capturing, further processing and recycling.

24. (Previously presented) An apparatus according to claim 23, further comprising a pasteurizer upstream and/or downstream of any of the cross-flow filtration modules for pasteurizing the milk source or any one or more filtration fractions generated by the cross-flow filtration modules.
25. (Previously presented) An apparatus according to claim 23, comprising multiple fluid delivery conduits arranged in a manner that each cross-flow filtration module is connected to at least one fluid delivery conduit, said fluid delivery conduits functioning to effectuate a flow of the milk or a fraction of the milk through each cross-flow filtration module.

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26. (Previously presented) An apparatus according to claim 23, further comprising temperature controller or monitor for controlling and monitoring temperature of said milk and/or filtration fractions generated by the cross-flow filtration modules.
27. (Previously presented) An apparatus according to claim 23, further comprising a cream separator upstream of said cross-flow filtration modules for removing all or at least a portion of fatty component from the milk.
28. (Previously presented) The apparatus of claim 1, wherein the milk source comprises a transgenic or hyper-immunized mammal.

the step of using the α -lactalbumin-rich fraction captured in step (i) to form infant formula.

39. (Previously presented) A system for sequentially fractionating milk, comprising:
 - (a) a source of milk;
 - (b) a first cross-flow filtration module in fluid communication with said source of milk for separating the milk into a casein-rich retentate fraction and a casein-depleted permeate fraction;
 - (c) a first fluid collection conduit connected to said first cross-flow filtration module for capturing the casein-rich retentate fraction;
 - (d) a second cross-flow filtration module in fluid communication with said first cross-flow filtration module for separating the casein-depleted permeate fraction into a protein concentrate fraction and a protein-depleted permeate fraction;
 - (e) a second fluid collection conduit connected to said second cross-flow filtration module for capturing or discharging the protein-depleted permeate fraction;
 - (f) a third cross-flow filtration module in fluid communication with said second cross-flow filtration module for separating the protein concentrate fraction into a β -lactoglobulin-rich fraction and a β -lactoglobulin-depleted permeate fraction;
 - (g) a third fluid collection conduit connected to said third cross-flow filtration module for capturing the β -lactoglobulin-rich fraction;

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- (h) a fourth cross-flow filtration module in fluid communication with said third cross-flow filtration module for separating the β -lactoglobulin-depleted fraction into an α -lactalbumin-rich fraction and an α -lactalbumin-depleted permeate fraction;
- (i) a fourth fluid collection conduit connected to said fourth cross-flow filtration module for capturing the α -lactalbumin-rich fraction; and
- (j) a fifth fluid collection conduit connected to said fourth cross-flow filtration module for capturing or discharging the α -lactalbumin-depleted permeate fraction.

40.-43, (Cancelled)

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Reasons for allowance

2. The following is an examiner's statement of reasons for allowance: claims 1-16, 19, 21-28, and 39 are allowed over the prior art of record. The apparatus arranged to comprise a source of milk and combination of cross-flow membrane filter modules to produce permeate and concentrate multi-fractions of different components in milk as in claims 13, 14, 23, 39 and dependent claims, which is not suggested in the prior art of record. The apparatus arrangement corresponds with steps in the process of parent patent 6,875,459, and is tailor to work with milk to produce the same specific fractions in each crossflow stage.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M. Fortuna whose telephone number is (571) 272-1141. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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